#### Attachment B:

Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92(c).



1.

GE Medical Systems

General Electric Company P.O. Box 414. Milwaukee, WI 53201

#### Section a):

Submitter:

**GE Medical Systems** 

PO Box 414

Milwaukee, WI 53201

Contact Person: Allen Schuh,

Manager, Safety and Regulatory Engineering

Telephone: 414-647-4385; Fax: 414-647-4090

Date Prepared: January 31, 2001

2. Device Name:

GE Model 2285873 Diagnostic Ultrasound System

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO

3. Marketed Device:

GE LOGIQ 500 diagnostic ultrasound system, 510(k) Numbers K933202, K951723,

K970901 and K991611 currently in commercial distribution.

- 4. <u>Device Description</u>: The GE Model 2285873 is a full featured general purpose diagnostic ultrasound system. It consists of a mobile console approximately 60 cm wide, 100 cm deep and 140 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and a color video CRT display This modification will provide users with significantly improved ergonomics, operation, maneuvering and ease of use.
- 5. <u>Indications for Use</u>: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal; Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, vascular and neurological).
- 6. <u>Comparison with Predicate Device</u>: The GE Model 2285873 is of a comparable type and substantially equivalent to the current GE LOGIQ 500. It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction, and materials, and has the same intended uses and basic operating modes as the predicate device.

#### Section b):

- 1. <u>Non-clinical Tests</u>: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
- 2. Clinical Tests: None required.
- 3. <u>Conclusion</u>: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Model 2285873 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

#### MAR - 1 2001

Mr. Allen Schuh
Manager, GE Ultrasound Safety and Regulatory Engineering
GE Medical Systems
P. O. Box 414
MILWAUKEE WI 53201

Re: K010329

GE Model 2285873 Diagnostic Ultrasound System

Dated: January 31, 2001 Received: February 2, 2001 Regulatory Class: II

21CFR §892.1550/Procode: 90 IYN 21CFR §892.1560/Procode: 90 IYO 21CFR §892.1570/Procode: 90 ITX

Dear Mr. Schuh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Model 2285873 Diagnostic Ultrasound system, as described in your premarket notification:

#### Transducer Model Number

3C 3.5/2.5 MHz Curved Array 5C 5.0/4.0 MHz Curved Array M7C 6.5/5.0 MHz Curved Array E8C 6.5/5.0 MHz Curved Array 7L 5.0/4.0 MHz Linear Array 10L 6.5/5.0 MHz Linear Array 12L 6.5/5.0 MHz Linear Array M12L 6.5/5.0 MHz Linear Array 3S 2.5/2.0 MHz Phased Array M3S 2.5/2.0 MHz Phased Array 4S 3.5/2.5 MHz Phased Array 5S 3.5/2.5 MHz Phased Array 7S 5.0/4.0 MHz Phased Array 10S 7.5.5.0 MHz Phased Array 6T 5.0/4.0 MHz Phased Array 2D 2.0 MHz Dual Array 6D 6.0 MHz Dual Array i8L 6.5/5.0 MHz Linear Array i12L 7.5/5.0 MHz Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850 j :

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.

Captain, USPHS

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

### Diagnostic Ultrasound Indications for Use Form

### GE Model 2285873 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic								<u> </u>			
Fetal / Obstetrics	Р	Р	Р	P	P	Р	Р	Р	P	Р	
Abdominal <sup>[1]</sup>	Р	Р	P	Р	Р	P	Р	P	Р	Р	
Pediatric	Р	Р	Р	Р	Р	Р	Р	Р	P	P	<u> </u>
Small Organ <sup>[2]</sup>	Р	P	Р		Р	P	Р	P	Р		
Neonatal Cephalic	P	Р	P	Р	Р	Р	Р	P	P	Р	
Adult Cephalic	P	Р	Р	Р	Р	P	Р	Р	P	P	
Cardiac <sup>[3]</sup>	Р	P	Р	P	<u>P</u>	Р	Р	Р	P	P	-
Peripheral Vascular	Р	Р	Р	Р	Р	P	P	Р	P	Р	-
Musculo-skeletal Conventional	Р	P	Р		Р	P	P	P	P	P	-
Musculo-skeletal Superficial	Р	Р	Р		Р	P	P	P	P	Р	-
Other <sup>[4]</sup>	Р	Р	Р	Р	<u>Р</u>	<u>Р</u>	Р	P	P	Р	┼
Exam Type, Means of Access					<u> </u>		<u> </u>	<u> </u>			-
Transesophageal	Р	Р	Р	P	P	P	P	P	P	<del> </del> -	-
Transrectal	Р	P	Р		P	<u> P</u>	P	P	P	ļ	-
Transvaginal	Р	P	P		P	P	P	P	P	-	+
Transuretheral					J	<u> </u>		ļ	<del> </del>	<del> </del>	
Intraoperative <sup>[5]</sup>	Р	Р	Р	Р	Р	<u>Р</u>	P	P_	<u> </u>	P	-
Intraoperative Neurological	P	Р	Р		Р	<u>Р</u>	P	P	P	P	-
Intravascular						<del> </del>		-			
Laparoscopic		1	ad by ED					_1		<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[1] Abdominal includes renal,	GYN/Pelvic
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology/Prostate
- [5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
- [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>KO1032</u> C

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### GE Model 2285873 with 3C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Othe
Ophthalmic							L				
Fetal / Obstetrics	Р	P	Р		Р	Р	Р	Р	P	Р	
Abdominal <sup>[1]</sup>	Р	P	P		P	P	Р	Р	P	P	-
Pediatric	Р	Р	P		Р	Р	Р	P	Р	Р	<u> </u>
Small Organ (specify)											<b>├</b>
Neonatal Cephalic						<u> </u>					<u> </u>
Adult Cephalic				ļ							-
Cardiac				ļ	ļ	<u> </u>			ļ		-
Peripheral Vascular					<u> </u>	<u> </u>			ļ		<del> </del>
Musculo-skeletal Conventional					<u> </u>	<u> </u>				-	<del> </del>
Musculo-skeletal Superficial			<u> </u>		<b>↓</b>	<del> </del>		-			-
Other <sup>[4]</sup>	Р	P	P	<u> </u>	P -	P	P	Р	Р	Р	<b></b>
Exam Type, Means of Access		ļ		<del> </del>	<b>↓</b>	<u> </u>	<u> </u>	<del> </del>	<del> </del>	<u> </u>	<del> </del>
Transesophageal					ļ	<del> </del>	<del> </del>	ļ	<u> </u>	<del> </del>	-
Transrectal					<del> </del>	<del> </del>	ļ	<del> </del>	<del> </del>	-	+
Transvaginal		<u> </u>		<u> </u>	<u> </u>	<del> </del>	<del> </del>		<del> </del>	-	
Transuretheral				ļ	<del> </del>	<b>-</b>		<del> </del>	<del> </del>		
Intraoperative (specify)		<u> </u>		<del> </del>	<del> </del>	<del> </del>	<del> </del>		<del>                                     </del>	<del> </del>	-
Intraoperative Neurological		-		<del> </del>	<del> </del>	<del> </del>	<del> </del>		1	-	-
Intravascular		<u> </u>		<u> </u>	<b>_</b>	-	<del> </del>		<del>                                     </del>	-	+-
Laparoscopic						<u> </u>		<u>. j </u>			<u> </u>

Intravascular										 
Laparoscopic								<u></u>		
N = new indication; P = pr	eviously	cleared	by FDA	i; E = a	dded und	der Appe	endix E			
Notes: [1] Abdominal incl	udes G\	YN;								
[4] Other use inclu	ides Urd	ology;								
[*] Combined mod	les are F	B/M, B/C	color M,	B/PWD,	B/Color	/PWD, E	3/Power/	PWD.		
.,										 
								IF NEEDED	)	 
	Co	oncurren	ce of CD	RH, Offic	ce of Dev	rice Eval	uation (O	IDE)		
							· _ ~			

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>K01632</u> 9

### Diagnostic Ultrasound Indications for Use Form

## GE Model 2285873 with 5C Transducer

e: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	•	Harmonic Imaging	Coded Pulse	Other
Anatomy/Region of Interest			1	<del>                                     </del>							
Ophthalmic					<del> </del>	Р	Р	Р	Р		
Fetal / Obstetrics	P	Р	P		P	<del></del>		P	P		
Abdominal <sup>[1]</sup>	P	Р	P	<u> </u>	P	P	P	P			
Pediatric				<u> </u>	<u> </u>	<del> </del>					
Small Organ (specify)					<b></b>	<u> </u>					-
Neonatal Cephalic					<u> </u>	<del> </del>	ļ	ļ			<u> </u>
Adult Cephalic				ļ		<u> </u>	<b>_</b>		<u> </u>		
Cardiac				<u> </u>			<u> </u>		<del> </del>	<u> </u>	├
Peripheral Vascular	Р	Р	P		Р	P	P	P	Р		
Musculo-skeletal Conventional					<u> </u>	<u> </u>	ļ	-			
Musculo-skeletal Superficial					<u> </u>	<del> </del>			<b></b>	<u> </u>	
Other <sup>[4]</sup>		<u> </u>			<u> </u>	ļ			-	<u> </u>	<del> </del>
Exam Type, Means of Access						<b> </b>	<del> </del>	ļ	<del> </del>	<del> </del>	┼─
Transesophageal					<b>_</b>	<u> </u>	ļ			-	┼
Transrectal						<b>↓</b>	<u> </u>	<del></del>		-	
Transvaginal					<u> </u>	<del> </del>	<del> </del>		<u> </u>	-	┼
Transuretheral							ļ		ļ	<del></del>	<del> </del>
Intraoperative (specify)					<u> </u>	<u> </u>			<del>                                     </del>		<del> </del>
Intraoperative Neurological						<u> </u>				<u> </u>	╁
Intravascular						<del> </del>		<del></del>			—
Laparoscopic  N = new indication; P = pr								<u> </u>			

Transvaginal			<u> </u>	ļ <u>.</u>	<del> </del>	╁	+	ļ	<del> </del>	-	$\vdash \lnot$
Transuretheral					ļ	<u> </u>	ļ	ļ	<del> </del>	<b>-</b>	├
Intraoperative (specify)				<u> </u>		<u> </u>		<del> </del>	<del> </del>	<u> </u>	├
Intraoperative Neurological				ļ		ļ	ļ	<del> </del>			
Intravascular			<u> </u>	<u> </u>	ļ	<u> </u>					├
Laparoscopic							1	<u> </u>			<u> </u>
N = new indication; P = p Notes: [1] Abdominal inc [*] Combined mod	ludes G	/N/Pelv	ic, Rena	and Ac	rta-iliac	artery;					
	(PLEASE I	DO NOT W	RITE BELO	w THIS LINE	CONTIN	UE ON ANO	OTHER PAG	E IF NEEDEL	D)		
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Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>KO1032</u>

# Diagnostic Ultrasound Indications for Use Form

# GE Model 2285873 with M7C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope					
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppier	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р	<u> </u>	Р	P	Р	P	P	P	
Abdominal	P	Р	Р		P	P	P	P	Р	Р	
Pediatric	Р	Р	Р		Р	Р	Р	Р	Р	Р	
Small Organ <sup>[2]</sup>	Р	Р	Р	<u> </u>	Р	Р	Р	P	Р	Р	-
Neonatal Cephalic				<u> </u>		<u> </u>	<del> </del>		· · ·		-
Adult Cephalic			<b></b>			<del> </del>		<del>                                     </del>			-
Cardiac					<del> </del>	<u> </u>	<del> </del>	<del> </del>	-	P	┢
Peripheral Vascular	P	P	P	ļ	Р	<u> </u>	P	P	P	<u> </u>	-
Musculo-skeletal Conventional		<u> </u>		ļ	<u> </u>	<del> </del>		<del>                                     </del>	-		╁╌
Musculo-skeletal Superficial		<u> </u>		ļ	ļ	<del> </del>		<del> </del>			╀╴
Other (specify)			<u> </u>		ļ	<u> </u>	<del> </del>				+
Exam Type, Means of Access					<b>_</b>	<del> </del>	<u> </u>	<del> </del>		<del> </del>	+
Transesophageal				<u> </u>		<del> </del>				-	╁╴
Transrectal		ļ				<del> </del>		<del></del> -		<del> </del> -	╁
Transvaginal		<u> </u>				<del> </del>			-		+-
Transuretheral				<del> </del>		<del> </del>	<del></del>		-		+-
Intraoperative (specify)					_				-		+-
Intraoperative Neurological		<del> </del>			_	<del> </del>	-	+		+	+
Intravascular	L		<del> </del>				+		-	+	+
Laparoscopic N = new indication; P = p											

1.0			1 1	1		ì	l	1		
Transrectal			<b> </b>					-		
Transvaginal		<u> </u>						-		
Transuretheral			ļ					<b>_</b>		
Intraoperative (specify)							<b> </b>			
Intraoperative Neurological			L			ļ	ļ	ļ		
Intravascular							ļ	<u> </u>		
Laparoscopic  N = new indication; P = po							<u> </u>	<u> </u>		Ì
Notes: [2] Small organ in	des are B/M, B/	Color M,	B/PWD,							
	(PLEASE DO NOT W	RITE BELOV	W THIS LINE	- CONTINU	E ON ANO	THER PAGE	IF NEEDER	))		
	Concurre	nce of CE	ORH, Offic	e of Dev		_		ginn	~	
Prescription User (Per 2	1 CFR 801.109	)			(Divis	ion Sign on of Re adiologic	-Off) producti cal Device	V ive, Abdo	minal, E	

### Diagnostic Ultrasound Indications for Use Form

# GE Model 2285873 with E8C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P		P	Р	Р	Р	Р		
Abdominal <sup>[1]</sup>	Р	Р	P		Р	P	P	Р	Р		
Pediatric					<u> </u>		<u> </u>				
Small Organ (specify)											
Neonatal Cephalic				<u> </u>	<u> </u>	ļ		-			<del>                                     </del>
Adult Cephalic				<u> </u>		<u> </u>	ļ	<del> </del>			<del>                                     </del>
Cardiac			<u> </u>	ļ	ļ	<del> </del>		<del> </del>			
Peripheral Vascular		<u> </u>		ļ		<del> </del>		<del> </del>			$\vdash$
Musculo-skeletal Conventional		Ļ		ļ	<u> </u>	<del> </del>		<u> </u>	ļ	<del> </del>	-
Musculo-skeletal Superficial		<u> </u>			<del> </del>	<b>├</b>	<del> </del> -	<del> </del>	<del> </del>		<del>                                     </del>
Other <sup>[4]</sup>	Р	P	Р	ļ	P_	P	P	P	P	ļ <u>-</u>	<del>                                     </del>
Exam Type, Means of Access		<u> </u>			<del> </del>		<del> </del>	-		<u> </u>	┢
Transesophageal		<u> </u>			<del> </del>	<del> </del>	+	+ -	<del> </del>		-
Transrectal	Р	Р	P	<del></del>	P	Р	P	P	P	<del> </del>	$\vdash$
Transvaginal	Р	P	P		<u> </u>	P_	P	Р	P	<del> </del>	+-
Transuretheral		<del> </del>			<del> </del>	+	-			-	+
Intraoperative (specify)		<u> </u>		<del> </del>	<b></b>	+		-		-	+-
Intraoperative Neurological		<del> </del>		<del> </del>	<del> </del>					+	+
Intravascular		-		<del></del>	<del> </del>	+	-		-		+
Laparoscopic											Щ

Laparoscopic						<u> </u>		<del></del>		
N = new indication; P = pr	eviously	cleared	by FDA	E = ac	ded und	der Appe	endix E			
Notes: [1] Abdominal incl										
[4] Other use inclu	udes Urc	logy/Pro	ostate;					~		
[*] Combined mod	des are E	3/M, B/C	olor M,	B/PWD,	B/Color.	/PWD, E	3/Power/	PWD.		
	(PLEASE D	O NOT WR	ITE BELOW	THIS LINE	· CONTINU	E ON ANOT	HER PAGE	IF NEEDED	)	
	Co	ncurren	ce of CD	RH, Offic	e of Dev	ice Eval	uation (C	DE)		

E-6

(Division Sign-Off)

and Radiological Devices

Division of Reproductive, Abdominal, ENT,

# Diagnostic Ultrasound Indications for Use Form

## GE Model 2285873 with 7L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope					
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	<b> </b>
Ophthalmic											-
Fetal / Obstetrics	Р	Р	P		P	P	Р	Р	Р		
Abdominal	Р	Р	P	<u></u>	Р	P	Р	Р	Р		_
Pediatric						<u> </u>					
Small Organ <sup>[2]</sup>	Р	Р	P		Р	P	Р	P	Р		-
Neonatal Cephalic				ļ		<b>↓</b>	<u> </u>				<u> </u>
Adult Cephalic				<u> </u>	<u> </u>	<b>├</b> -	<del> </del>				$\vdash$
Cardiac		<u> </u>			<b>_</b>	<b></b>	ļ <u>-</u> -	<del> </del>			-
Peripheral Vascular	Р	Р	P	<b>_</b>	P	P	P	P	P		<del>                                     </del>
Musculo-skeletal Conventional	Р	P	P		P	<u>P</u>	P	P			<del>                                     </del>
Musculo-skeletal Superficial	P	P	Р	<del> </del> -	P	Р_	P	P	P		$\vdash$
Other <sup>[4]</sup>				<del></del>	<b>-</b>	<del> </del>	<del> </del>		<del> </del>		$\vdash$
Exam Type, Means of Access		<u> </u>	<del></del>		<del> </del>	+		<del> </del>	-	<del> </del>	+-
Transesophageal		<u> </u>				<del> </del>	<u> </u>		<del> </del>	<del>                                       </del>	+
Transrectal				<del> </del>	<del> </del>	<del></del>	<del> </del>	-		-	+-
Transvaginal		ļ	_		<b>_</b>	+	+		-	<b>-</b>	+
Transuretheral		-			-	+	<del> </del>	-		1	+
Intraoperative (specify)	<u> </u>	<del> </del>		-		+	<del> </del>	+	-	<del> </del>	+
Intraoperative Neurological		ļ		<del>                                     </del>		+	+	<del> </del>	<del> </del>	1	+
Intravascular		-		+			-		+		+-
Laparoscopic  N = new indication: P = p	<u> </u>			<u> </u>		<del></del>			<u> </u>	1	

mmaraoouia.				1			1		1	i	
Laparoscopic			L								<u></u>
N = new indication; P = pr	eviously	cleared	by FDA	E = ac	dded und	der Appe	endix E				
Notes: [2] Small organ in	cludes b	reast, te	stes, th	yroid.				D. 4.0			
[*] Combined mod	les are E	3/M, B/C	olor M,	B/PWD,	B/Color/	PWD, B	s/Power/	PWD.			
	(PLEASE	DO NOT WE	TE BELOV	THIS LINE	- CONTINU	E ON ANOT	HER PAGE	IF NEEDED	)		
	Co	oncurren	ce of CD	RH, Offic	ce of Dev	ice Eval	uation (C	DE)			

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>KO10329</u>

### Diagnostic Ultrasound Indications for Use Form

### GE Model 2285873 with 10L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

				<b>&gt;</b> 5.	Mode	of Ope			<del></del> 1	— т	
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	P	P		P	Р	Р	Р	Р	Р	
Abdominal	Р	Р	Р		Р	P	P	P	Р	Р	
Pediatric	Р	P	Р		Р	Р	Р	Р	Р	P	
Small Organ <sup>[2]</sup>	Р_	Р	P		P	Р	P	Р	Р	Р	
Neonatal Cephalic				<u> </u>	<u> </u>			<u> </u>			_
Adult Cephalic		<u> </u>		<u> </u>					<del> </del>		-
Cardiac			ļ	<u> </u>	<u> </u>	<u> </u>			<del> </del>		
Peripheral Vascular	Р	Р	P		P	P	Р	P	Р	P	-
Musculo-skeletal Conventional	Р	P	P	ļ	P	P	P	Р	P	P	_
Musculo-skeletal Superficial	P	P	P		P	P	P	P	Р	P	_
Other (specify)		<u> </u>					ļ.——				$\vdash$
Exam Type, Means of Access		<u> </u>			<u> </u>	ļ			-		├
Transesophageal		<u> </u>			<del> </del>	<u> </u>					-
Transrectal	,			<del> </del>	-	<del> </del>	<b>_</b>	<del> </del>		<u> </u>	_
Transvaginal				ļ	<u> </u>	<del> </del>	<u> </u>	-	<del> </del>	<del> </del>	$\vdash$
Transuretheral				ļ	ļ —	<u> </u>	<del> </del>			<del> </del>	-
Intraoperative <sup>[5]</sup>	Р	P	P		Р	P	P	P	P	P	╁
Intraoperative Neurological	Р	P	P		Р	P	P	P	P	P	+
Intravascular				ļ	<del> </del>	<b></b>	<del> </del>	<u> </u>	1		+
Laparoscopic					1		1,		<u> </u>		

Laparoscopio	
N = new indication; P = pre	eviously cleared by FDA; E = added under Appendix E
[5] Intraoperative i	cludes breast, testes, thyroid. includes abdominal, thoracic, and vascular. Neurosurgical added via K970901. les are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
	(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>KO10329</u>

## Diagnostic Ultrasound Indications for Use Form

# GE Model 2285873 with 12L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope		<del></del>		<del></del>	
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics					<u> </u>						$\vdash$
Abdominal			<u> </u>			ļ	<b>_</b>				
Pediatric	Р	Р	P		<u> P</u>	P	P	P	Р		├
Small Organ <sup>[2]</sup>	Р	Р	P	ļ	P	Р	P	P	Р		-
Neonatal Cephalic	, <u>,</u>			<u> </u>		<b>↓</b>			<u> </u>		<del>                                     </del>
Adult Cephalic			ļ		<u> </u>	<u> </u>	ļ				-
Cardiac			<u> </u>		<del> </del>	<u> </u>		<del> </del> -		<u> </u>	+-
Peripheral Vascular	Р	Р	P	ļ	P	<u> </u>	P_	P	P	ļ	$\vdash$
Musculo-skeletal Conventional	P	P	P	<del> </del>	P	P	Р	P	P		$\vdash$
Musculo-skeletal Superficial	Р	P	P	<u> </u>	P	P	P	P	P	<del> </del>	+
Other (specify)		<u> </u>			<b>_</b>	<del> </del>		<del> </del>			+-
Exam Type, Means of Access				<u> </u>	<u> </u>	<del> </del> -		<del> </del>	-	<del> </del>	+
Transesophageal		<u> </u>	<u> </u>		<del> </del>	<del> </del>	<del> </del>			<u> </u>	+
Transrectal					<b>-</b>		-	<del> </del>			+
Transvaginal		<u> </u>			<b>_</b>	<del> </del>		+		+	+
Transuretheral		ļ				+		+	<del> </del>	<del> </del>	+
Intraoperative [5] (specify)	Р	P	P	<del> </del>	P	P	P	P	P		+-
Intraoperative Neurological		<del>                                     </del>		<u> </u>		<del> </del>	+-	-	+	+	+
Intravascular	ļ	<del> </del>			-			+			+
Laparoscopic  N = new indication: P = 0											

Intravascular	<del></del>	<del>-  -</del>		<del></del>	<del></del>			T
Laparoscopic					<u> </u>	<u> </u>	1	 <del></del>
N = new indication; P = p				ınder App	oendix E			
Notes: [2] Small organ i	ncludes breast,	testes, thyro	id.					
[5] Intraoperative	includes abdo	minal, thorac	ic, and vas	cular.				
[*] Combined mo	des are B/M, B	/Color M, B/I	PWD, B/Co	lor/PWD,	B/Power	/PWD.		
						<del>.</del>		 
	(PLEASE DO NOT	AIDITE DELOW TH	IS LINE CONT	INUE ON ANO	OTHER PAGE	IF NEEDED	))	
	CONCULT	ence of CDRI	Office of E	evice Eva	luation (C	DDE)		

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K0103

#### Diagnostic Ultrasound Indications for Use Form

#### GE Model 2285873 with M12L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		<u> </u>	DIA	CW		of Ope		Combined	Harmonia	Coded	Г
	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Imaging	Pulse	
Anatomy/Region of Interest			Dobbiei	Doppiei	Dobbie	Dobbie	Dobbiei	14100163	magnig	. 4100	-
Ophthalmic			ļ								<u> </u>
Fetal / Obstetrics											
Abdominal											L
Pediatric	P	P	P		Р	P	P	Р	P	Р	L
Small Organ <sup>[2]</sup>	Р	Р	Р		Р	Р	P	Р	P	P	
Neonatal Cephalic											_
Adult Cephalic											-
Cardiac											
Peripheral Vascular	P	Р	Р		Р	Р	Р	P	P	Р	_
Musculo-skeletal Conventional	Р	P	Р		Р	P	Р	Р	Р	P	L
Musculo-skeletal Superficial	Р	Р	P		Р	Р	P	Р	Р	P	_
Other (specify)											L
Exam Type, Means of Access											L
Transesophageal											L
Transrectal	-										
Transvaginal			<u> </u>								L
Transuretheral											L
Intraoperative [5] (specify)	P	Р	Р		Р	Р	Р	Р	P	P	L
Intraoperative Neurological											
Intravascular											L
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [2] Small organ includes breast, testes, thyroid.
[5] Intraoperative includes abdominal, thoracic, and vascular.
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) 7
Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number \_\_\_\_

### Diagnostic Ultrasound Indications for Use Form

### GE Model 2285873 with 3S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope		1			
Clinical Application	В	м	PW	CW	Color	Color M			Harmonic	Coded Pulse	
Anatomy/Region of Interest			Doppler	Doppler	Doppler	Doppler	Doppler	Modes	Imaging	ruise	
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р	Р	Р	Р	Р	P	Р	Р	
Abdominal <sup>[1]</sup>	Р	Р	P	Р	Р	Р	Р	Р	Р	P	
Pediatric	P	Р	P	Р	Р	Р	Р	Р	Р	Р	_
Small Organ (specify)			<u> </u>			<u> </u>	ļ	ļ			$\vdash$
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Р	P	Р	_
Adult Cephalic	Р	Р	Р	Р	P.	Р	Р	Р	Р	Р	_
Cardiac <sup>[3]</sup>	Р	Р	Р	Р	Р	P_	Р	P	Р	Р	_
Peripheral Vascular			ļ			<u> </u>			ļ		_
Musculo-skeletal Conventional			ļ		ļ. <u></u>	<u> </u>		ļ			-
Musculo-skeletal Superficial		<u> </u>							<b> </b>		$\vdash$
Other <sup>[4]</sup>	Р	P	Р	Р	P	Р	P	P	Р	Р	┞
Exam Type, Means of Access			ļ		ļ	ļ			<u> </u>		-
Transesophageal					ļ	<u> </u>	ļ <u> </u>	<del> </del>	ļ	<u></u>	┼
Transrectal					<b></b>	<u> </u>	<u> </u>	<u> </u>		ļ	╀
Transvaginal		ļ	<u> </u>		ļ	<del> </del>		<u> </u>		<u> </u>	-
Transuretheral		ļ		ļ	<b></b>	<del> </del>	-	<u> </u>	<del> </del>		╀-
Intraoperative (specify)		<u> </u>			<b></b>	<del> </del>	<u> </u>		<b></b>		$\vdash$
Intraoperative Neurological		<u> </u>			J	<del> </del>	<del> </del>	<del> </del>	-	-	+
Intravascular				-	<b></b>	<del> </del>	ļ	-	-		+
Laparoscopic					<u></u>						<u> </u>

ITILI a vascolai					·	r	T		T		1
Laparoscopic							<u></u>	<u></u>	<u> </u>		<u></u>
N = new indication; P =	previously	cleared b	y FDA	E = ac	dded und	der Appe	endix E				
Notes: [1] Abdominal i	ncludes G\	'N;									
[3] Cardiac is A	dult and Po	ediatric;									
[4] Other use in	ncludes Urd	logy;									
[*] Combined n	nodes are E	3/M, B/Co	olor M,	B/PWD	or CWD	, B/Colo	r/PWD o	or CWD,	B/Power/	/PWD.	
									<del></del>		
	(PLEASE [	O NOT WRIT	E BELOW	THIS LINE	- CONTINU	E ON ANOT	HER PAGE	IF NEEDEC	))		
		ncurrence									

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number.

## Diagnostic Ultrasound Indications for Use Form

## GE Model 2285873 with M3S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope		r		<del></del>	
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	1 • 1	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P	Р	Р	Р	Р	Р	Р		
Abdominal <sup>[1]</sup>	Р	Р	Р	Р	Р	Р	Р	P	Р		
Pediatric	Р	Р	Р	Р	Р	Р	Р	P	Р		<del> </del>
Small Organ (specify)					<u> </u>	ļ	ļ				<del> </del>
Neonatal Cephalic	Р	Р	Р	P_	P	Р	Р	P	Р		<del> </del>
Adult Cephalic	P	P	Р	<u>P</u>	P	P	P	P	Р		-
Cardiac <sup>[3]</sup>	Р	Р	P	Р	P	P	Р	Р	Р		├─
Peripheral Vascular					ļ	<u> </u>	<del> </del> -	<del> </del>	<u> </u>		├
Musculo-skeletal Conventional				ļ	<u> </u>	<u> </u>		<del> </del>			-
Musculo-skeletal Superficial				<del> </del>	<u> </u>	<del> </del>		+			$\vdash$
Other (specify)	Р	P	P	P	P	P	P	P	P		├-
Exam Type, Means of Access		<u> </u>		ļ	<del> </del>	<del> </del>	-		-	<del> </del>	┼
Transesophageal		<u> </u>	<del></del>	ļ	ļ	<u> </u>	<del> </del>	<del> </del>	-	<del> </del>	+
Transrectal		<u> </u>				<del> </del>	<del> </del>				╁
Transvaginal		<del>                                     </del>			1	<u> </u>		<del>                                     </del>	-	-	+-
Transuretheral					<b></b>	<b></b>	-	<del>                                     </del>	<del>                                     </del>		+
Intraoperative (specify)			_			<del> </del>	-			-	+
Intraoperative Neurological		<u> </u>				<del> </del>	<del> </del>			<del> </del>	+
Intravascular		ļ			<del> </del>	+	-	+	-	-	+
Laparoscopic							<u> </u>			<del></del>	1_

Laparoscopic	
I = new indication; P = pr	eviously cleared by FDA; E = added under Appendix E
Notes: [1] Abdominal incl	udes Renal and GYN;
[3] Cardiac is Adu	It and Pediatric.
[4] Other use inclu	ides Urology;
[*] Combined mod	des are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
	(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of Device Evaluation (ODE)
	Concurrence of Opticity, Street Control Desires

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>RO10329</u>

# Diagnostic Ultrasound Indications for Use Form

# GE Model 2285873 with 4S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope		, <sub></sub>			
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppier	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N_	N	N	N	N	
Abdominal <sup>[1]</sup>	N	N	N	N_	N	N	N	N	N	N	
Pediatric	N	N	N_	N	N	N	N	N	N	N	
Small Organ (specify)				<u> </u>			<del> </del>	<del> </del>			
Neonatal Cephalic	N	N	N	N	N_	N	N	N	N	N	
Adult Cephalic	N	N	N	N	N	N	N N	N	N	N	-
Cardiac <sup>[3]</sup>	_ N	N	N	N	N	N_	N_	N	N	N	-
Peripheral Vascular				ļ	<u> </u>	<del> </del>		<u> </u>			-
Musculo-skeletal Conventional		<u> </u>		ļ	<u> </u>	<del> </del>	ļ	<del> </del>			-
Musculo-skeletal Superficial					<del> </del>	<del> </del>	<del> </del>		<del> </del>	N	$\vdash$
Other (specify)	N	N	N	N	<u> </u>	N	N	N	N	I N	-
Exam Type, Means of Access		<u> </u>		<del> </del>	<u> </u>	<u> </u>	<del> </del>	-		-	+
Transesophageal		<u> </u>			<del> </del>	<del> </del>			<del> </del>		+-
Transrectal		ļ		<del> </del>	<del> </del>	<del> </del>		1	<del>                                     </del>	<del> </del>	$\dagger$
Transvaginal				ļ		+			<del>                                     </del>		+
Transuretheral		-		<del> </del> -	<del> </del>	+	+	+		+	+-
Intraoperative (specify)		<del> </del>			+		<del> </del>	+		1	+
Intraoperative Neurological		+	_	<del> </del>	<del> </del>		+		-	1	+-
Intravascular	<u> </u>				<del> </del>	+	+				+
Laparoscopic		<u> </u>		<u></u> _		4			ــــــــــــــــــــــــــــــــــــــ		ــــــــــــــــــــــــــــــــــــــ

Laparoscopic						<u></u>				=
N = new indication; P = pro	eviously clea	red by FDA	K; E = ac	ided und	der Appe	endix E				
Notes: [1] Abdominal incli	udes Renal a	nd GYN;								
[3] Cardiac is Adul	lt and Pediatr	ric.								
[4] Other use inclu	ides Urology;							S.D(	DWD.	
[*] Combined mod	ies are B/M, I	3/Color M,	B/PWD	or CWD	, B/Colo	r/PWD c	or CWD,	B/Power/	PWD.	
										-
								<del> </del>		-
	(PLEASE DO NOT	WRITE BELOV	V THIS LINE	CONTINU	E ON ANO	THER PAGE	IF NEEDED	)		_
	Concur	rence of CD	RH, Offic	e of Dev	rice Eval	uation (C	DE)			

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number KO1032

# Diagnostic Ultrasound Indications for Use Form

# GE Model 2285873 with 5S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

1					Mode	of Ope					
Clinical Application	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic   Imaging	Coded Pulse	
Anatomy/Region of Interest				<del></del>							
Ophthalmic			<del> </del>		P	P	Р	Р	Р		
Fetal / Obstetrics	P	<u> </u>	Р	P	<del></del>	<del> </del> -	P	P	Р		
Abdominal <sup>[1]</sup>	Р	P	P	P	P	P	<del>                                     </del>	<del> </del>	P		
Pediatric	Р	P	P	P	P	P	P	Р	-	<del> </del>	
Small Organ (specify)			<u> </u>	<del> </del>	<del>                                      </del>	<del> </del>	<del> </del>	<del>                                     </del>			
Neonatal Cephalic				ļ	<del> </del>	<del> </del>	<del> </del> _	P	P	<b> </b>	1
Adult Cephalic	Р	Р	P	P	P	P	P		P		1
Cardiac <sup>[3]</sup>	Р	P	P	P	P	P	P	P	P		<del>                                     </del>
Peripheral Vascular				ļ		<del> </del>	<del> </del>	<del> </del>	-		+-
Musculo-skeletal Conventional			<del></del>		<del> </del>		<del> </del>		1	<del> </del>	+
Musculo-skeletal Superficial					<b></b>	<del></del>	ļ	<del> </del>	P	ļ	-
Other <sup>[4]</sup>	Р	P	P	P	<u> </u>	<u>P</u>	P	P	P	<del>                                     </del>	+
Exam Type, Means of Access				<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	-	<del> </del>
Transesophageal		<u> </u>			<u> </u>				+	+	$\top$
Transrectal		<u> </u>			<del> </del>	<del> </del>	<del></del>		+	<del> </del>	+
Transvaginal						<del> </del>		_	+	+	+-
Transuretheral		ļ						_			+
Intraoperative (specify)	ļ				<del> </del>	+				+	+-
Intraoperative Neurological	ļ	<del> </del>						+			$\dashv$
Intravascular	<u> </u>						_	_	<del> </del>	-	+
Laparoscopic  N = now indication: P = n									<u> </u>		L_

Laparoscopic					
N = new indication; P = pr	eviously clea	red by FDA	E = a	added under Appendix E	
Notes: [1] Abdominal incl	udes GYN;				
[3] Cardiac is Adu					
[4] Other use inclu [*] Combined mod	udes Urology ies are B/M,	; B/Color M,	B/PWD	O or CWD, B/Color/PWD or CWD, B/Power/PWD.	
	(PLEASE DO NO	T WRITE BELOV	V THIS LINE	NE CONTINUE ON ANOTHER PAGE IF NEEDED)	
	Concu	rrence of CE	RH, Offi	ffice of Device Evaluation (ODE)	

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) 1
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number (010) 5.

#### Diagnostic Ultrasound Indications for Use Form

#### GE Model 2285873 with 7S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	· · · · · · · · · · · · · · · · · · ·				Mode	of Ope	ration				
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P	P	Р	Р	Р	Р	P		
Abdominal <sup>[1]</sup>	Р	Р	P	P	Р	Р	Р	Р	P		
Pediatric	Р	P	Р	Р	P	Р	Р	Р	P		
Small Organ (specify)											
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Р	P		
Adult Cephalic	P	Р	P	Р	Р	Р	P	Р	Р		
Cardiac <sup>[3]</sup>	Р	P	P	Р	Р	P	Р	Р	Р		
Peripheral Vascular			<b></b>					ļ			
Musculo-skeletal Conventional			ļ								
Musculo-skeletal Superficial				ļ							
Other (specify)		ļ	<u> </u>								
Exam Type, Means of Access				ļ		ļ — —					
Transesophageal				<u> </u>	ļ	<del> </del>		<b> </b>			
Transrectal		ļ		<u> </u>	<u></u>	<del> </del>	ļ				
Transvaginal		ļ <u>.</u>	<b>_</b>	ļ		<del> </del> -	ļ. <del></del>	<del> </del>			
Transuretheral		ļ	<del></del>	<u> </u>	<del> </del>					ļ	
Intraoperative (specify)		<u> </u>		<u> </u>	<del>  -</del> -				<u> </u>	<u> </u>	-
Intraoperative Neurological		ļ			<del> </del> -	<del> </del> -	ļ	1			-
Intravascular				<u> </u>	<u> </u>	<del> </del> -	ļ		ļ		-
Laparoscopic		<u></u>	<u> </u>	<u> </u>		<u> </u>				<u> </u>	<u> </u>

	= new indication: P :		-1	. [ ]		under	Accordiv i	_
NI.	– naw indication: D :	- proviniely	CIASTAN N	/ III ) AI `	$\mathbf{F} = \mathbf{a} \mathbf{c} \mathbf{c} \mathbf{e} \mathbf{c}$	ппоег.	ADDEROIX I	_
14 3	= new mulcanon, r ·	- 0164100314	Cleared by	, , ,,	aaaaa			_

Notes:	[4]	Abdom	inal inc	dudoc	GVN:
Notes:	111	Andom	เทลเ เทด	าเมตคร	GYN:

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology and GYN.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

				· ·		
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(,						

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K010329</u>

## Diagnostic Ultrasound Indications for Use Form

# GE Model 2285873 with 10S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope			т		
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic							<u> </u>	-			
Fetal / Obstetrics			ļ			<del> </del>	<del></del>				
Abdominal	Р	Р	P	P	Р	P	P	P	P		-
Pediatric	P	Р	Р	Р	P_	P	P	P	Р	<u> </u>	-
Small Organ (specify)			ļ		ļ		<del>  </del>	-	P		
Neonatal Cephalic	Р	Р	P	Р	P	P	P	P	P		$\vdash$
Adult Cephalic	Р	Р	P	P	P	P	P	P	P	<del> </del>	<del>                                     </del>
Cardiac <sup>[3]</sup>	Р	P	P	P_	P	P	P	P	<u> </u>	<del> </del>	-
Peripheral Vascular					<u> </u>	<del> </del>	<del> </del>	<del> </del>	<u> </u>	<del> </del>	-
Musculo-skeletal Conventional		<u> </u>	<b>-</b>			<del></del>	<del> </del>	+		-	+-
Musculo-skeletal Superficial			<u> </u>	<del></del>	<del> </del>		<del> </del>		-	<del> </del>	_
Other (specify)		<del> </del>	<del> </del>	<del> </del>		<del> </del>	-	<del> </del>	<u> </u>	╁┈╌╴	+
Exam Type, Means of Access				<del> </del>			-	+	+	<del> </del>	+
Transesophageal		ļ	<del> </del>			<del> </del>		<u> </u>		1	+
Transrectal		<u> </u>			<del> </del>			-		+	+-
Transvaginal				<b>-</b>	<del></del>	<del> </del>		-	-		+-
Transuretheral	ļ	-	-	-			<del> </del>	<del> </del>	-		+
Intraoperative (specify)	<b></b>	<del> </del>			+		+	-	+	+	+-
Intraoperative Neurological	<del> </del>	<del>  </del>		-	-	+			+	+	+
Intravascular								+		+	+-
Laparoscopic					4	<del></del> _	<u> </u>	<u></u>			

Laparoscopic							<u> </u>				
N = new indication; P =	previously	cleared t	y FDA	E = ac	ided und	ler Appe	endix E	=			
Notes: [3] Cardiac is Ad [*] Combined m	fult and P	ediatric							D, B/Pow	er/PWD.	
	(D) 5405	DO NOT WRIT	re BELOW	THIS LINE	- CONTINU	 E ON ANO	THER PA	GE IF NEED	)ED)		
	C	oncurrence	e of CD	RH, Offic	e of Dev	ice Eval	uation	(ODE)			

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

#### Diagnostic Ultrasound Indications for Use Form

### GE Model 2285873 with 6T Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope		<del></del> 1	<del>1</del>	—— т
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse
Ophthalmic			ļ			<del></del>				
Fetal / Obstetrics										
Abdominal			<u> </u>				<u> </u>			
Pediatric				ļ		<u> </u>		<u> </u>	ļ	
Small Organ (specify)							ļ	<del> </del>	<u> </u>	
Neonatal Cephalic				ļ	<u> </u>	<u> </u>	<u> </u>			
Adult Cephalic			ļ	<u> </u>		<del> </del> -	ļ <u>-</u>	-	<del> </del>	
Cardiac	Р	P	P	Р	P _	P _	P	P	P	<del>  </del>
Peripheral Vascular					<u> </u>	<u> </u>	<u> </u>	-		
Musculo-skeletal Conventional					ļ	<del> </del> -	ļ	<u> </u>		
Musculo-skeletal Superficial				<u> </u>	<u> </u>			ļ	ļ	
Other (specify)		<u> </u>			ļ	<del> </del> -	<del> </del>		<u> </u>	
Exam Type, Means of Access					<u> </u>	<del> </del> _	<del> </del> -	<b>-</b>		<u> </u>
Transesophageal	Р	р	P	P	<u> </u>	<u> </u>	P	P	P	<u> </u>
Transrectal		<u> </u>	<b>_</b>	<u> </u>	<del> </del>	<del> </del> -	<del> </del>		<del> </del>	
Transvaginal		ļ		<del></del> -	ļ	<del> </del> -				
Transuretheral						<del> </del> -	ļ		<b>}</b> -	-
Intraoperative (specify)		<u> </u>		<u> </u>		<del> </del> -	<b> </b>			<del> </del>
Intraoperative Neurological		ļ						<del> </del>	<del> </del>	
Intravascular		<u> </u>	_		<del> </del> -	<del></del> -	<del> </del>	-	<del>                                     </del>	
Laparoscopic				] A; E = a	<u> </u>	٠	<u> </u>		<u> </u>	<u> </u>

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K010329

#### Diagnostic Ultrasound Indications for Use Form

#### GE Model 2285873 with 2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		4.4	PW	cw	Color	of Ope		Combined	Harmonic	Coded	
Anatomy/ Region of Interest	В	М	Doppler		Doppler	Doppler	Doppler		Imaging	Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>				P							
Peripheral Vascular				P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)									:		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)			<u> </u>								
Intraoperative Neurological											
Intravascular											
Laparoscopic		]						1		İ	

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) 
Division of Reproductive, Abdominal, ENT, and Radiological Devices

10(k) Number K01032

## Diagnostic Ultrasound Indications for Use Form

## GE Model 2285873 with 6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

				Mode	of Ope			——-		
В	М	PW Doppler	CW Doppler	Color	Color M		1	Harmonic Imaging	Coded Pulse	1
	<u> </u>	Sophier	- SPPICI				+	<u> </u>	<del>-  </del>	<del></del>
	<u></u>	-	<del></del>	<del></del>	<b></b>	<del></del>		<b></b>	<b></b>	<del></del>
		<del> </del>	<del></del>	$\longrightarrow$	L	Щ-	<del></del>	<del></del>	<del></del>	<b></b>
	L	<del> </del>	<del></del>	<b>├</b>	L	Щ-	<b></b>	<b>—</b>		<b></b>
		-		L	<del></del>	<u></u>	-	<del></del>	<del></del>	<del></del>
			-	<del></del>	<del></del>	<u> </u>	-	<del></del>	<del></del>	-
		1	ļ	<b>├</b>	L	L	<del></del>	<del></del>	<del>                                     </del>	<del></del>
`			ļ		<b></b>	<b>—</b>			-	<del></del>
	ļ		Р	<b></b>	<b></b>	L		-	-	<del> </del>
			Р	<del></del>	<del> </del>				<del> </del>	<b>—</b> —
		-		<del></del>	<del> </del>	<b></b>	-	<del> </del>	<del></del>	-
					<del> </del>	<u> </u>			<del> </del>	+
			<del> </del>	<del></del>	<del></del>	<del></del>				+
	ļ			<b></b>	<del></del>	<del> </del>		-	<del></del>	+
				<del></del>	<del></del>	<del> </del>	<del> </del>	-	-	+
			<b> </b>	<del></del>		<del> </del>	-		+	-
	<u></u>				<del></del>	<del> </del>	<del> </del>	-	+	
	<u></u>			<del></del>	<del></del>	<b>_</b>		-	-	
			<u> </u>	<b></b>	<del> </del>	-	<del> </del>		-	+
	<u></u>			<del></del>	-	<b></b>	<del></del>	-	+	+-
	<u></u>			-				<del> </del>	+	+
					<u></u>	<u></u>		<u></u>		<u></u>
revious ult and F	ly clear Pediatric	ed by FD c.	A; E={	added ur	nder Apr	pendix Ē				
(PLEASE	DO NOT V	VRITE BELO	W THIS LINE	E - CONTINU	JE ON ANO.	THER PAGE	E IF NEEDED	<u>)</u>		
	previously ult and F	reviously cleareult and Pediatric	Doppler  Doppler  Doppler  Doppler  Doppler  Doppler  Doppler	Doppler Doppler  Doppler Doppler  P  P  P  P  P  P  P  P  P  P  P  P  P	B M PW Doppler	B M PW Doppler	B M PW Doppler	B M PW Doppler Doppler Doppler Doppler Doppler Doppler Modes	B M PW Doppler CW Doppler Doppler Doppler Doppler Doppler Combined Harmonic Imaging  PW Doppler Doppler Doppler Doppler Doppler Doppler Modes Imaging  PP P P P P P P P P P P P P P P P P P	B M PW Doppler

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

#### Diagnostic Ultrasound Indications for Use Form

#### GE Model 2285873 with i8L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	ration				
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	Р	Р	P		Р	Р	Р	Р	Р		
Pediatric			ļ								
Small Organ (specify)			<b>_</b>								-
Neonatal Cephalic											
Adult Cephalic	<u></u>										
Cardiac <sup>[3]</sup>	Р	P	P		Р	P	P	P	Р		_
Peripheral Vascular								<u> </u>			_
Musculo-skeletal Conventional				ļ <u> </u>		<u> </u>		<u> </u>	ļ		
Musculo-skeletal Superficial					<u> </u>						
Other (specify)		<u> </u>	ļ			<u> </u>					_
Exam Type, Means of Access							ļ	-	ļ		ļ
Transesophageal					<u> </u>			<u> </u>	<u> </u>		<del> </del>
Transrectal		<u> </u>			ļ						<u> </u>
Transvaginal		<u> </u>							<u></u>		_
Transuretheral					ļ						<u> </u>
Intraoperative <sup>[5]</sup>	Р	P	Р	<u> </u>	Р	P	Р	P	Р		-
Intraoperative Neurological		ļ				<u> </u>	ļ	<del> </del>	<u> </u>		-
Intravascular		ļ				ļ	ļ	ļ	<del> </del>		-
Laparoscopic				<u> </u>		<u></u>				<u> </u>	<u></u>

N = new indica	ation; P = previously cleared by FDA; E = added under Appendix E
Notes: [1] Abo	dominal is via Intraoperative;
[3] Ca	rdiac is Adult and Pediatric via Intraoperative;
[5] Intr	aoperative includes abdominal, thoracic, and vascular.
(*) Cor	mbined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
	(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number

## Diagnostic Ultrasound Indications for Use Form

## GE Model 2285873 with i12L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	!	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic									`		<del>                                     </del>
Fetal / Obstetrics											
Abdominal <sup>(1)</sup>	Р	Р	Р		<u>P</u> _	P	P	Р			<del>                                     </del>
Pediatric				<u> </u>	<del> </del> -						$\vdash$
Small Organ (specify)			ļ					<del> </del>	<b> </b>		+
Neonatal Cephalic						<del> </del> -					$\vdash$
Adult Cephalic			<u> </u>	<del> </del>	<del> </del>	<del> </del>			<del>                                     </del>		+
Cardiac <sup>[3]</sup>	Р	Р	P	<del> </del>	P	Р_	Р	P	<del> </del>	<del>                                     </del>	+-
Peripheral Vascular		ļ		<del></del>	<del></del>	<del> </del> -		<del>                                     </del>		<del> </del>	+-
Musculo-skeletal Conventional		ļ			<del> </del>	<del> </del> -		<del> </del>		<del>                                     </del>	+
Musculo-skeletal Superficial		<u> </u>			<del> </del> -	<del> </del>		<del> </del>			+
Other (specify)			<u> </u>	<del> </del>	<del> </del>					<del> </del>	+-
Exam Type, Means of Access		<del>                                     </del>	<del> </del>	<del> </del>	<del> </del>	-			<del> </del>	<del>                                     </del>	+
Transesophageal				<del> </del>	<del> </del>	<del> </del> -		1	-	<del> </del>	+-
Transrectal		<u> </u>		+	<del> </del>	+	<del> </del>	<del> </del>		<b></b>	+
Transvaginal		ļ			<del> </del>					+	+-
Transuretheral		<del> </del>	_		<del></del>	<del> </del>	+-	-	-	<del>                                     </del>	+
Intraoperative <sup>[5]</sup>	Р	P	Р		P	<u> </u>	P	P			$\dagger$
Intraoperative Neurological		<del> </del>		+		+	+	-		+	+
Intravascular		4		+	<del> </del>		+	+		+	+
Laparoscopic  N = new indication: P = p	<u> </u>										

Laparoscopic								
N = new indication; F	= previously	cleared by FDA	: E = ad	ded unde	er Appe	ndix E		
Notes: [1] Abdomina [3] Cardiac is	Adult and Ped	erative; diatric via Intrad abdominal, thoi	operative	; i vascula	ar.			
[5] Intraopera [*] Combined	I modes are B/	M, B/Color M,	B/PWD,	B/Color/F	PWD, B	/Power/F	PWD.	 
							- NEEDED)	 
	(PLEASE DO	NOT WRITE BELOW	THIS LINE	CONTINUE	ON ANOT	HER PAGE	F NEEDED!	 
	Cor	ncurrence of CD	RH, Offic	e of Devi	ce Evalu	ation (O	DE)	

Prescription User (Per 21 CFR 801.109)

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510(k) Number KC10329